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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/736,489	12/15/2003	Xia Zhao	4133-031323 (P-6125)	3805	
32182	32182 7590 10/07/2005			EXAMINER	
DAVID W. H	HIGHET, VP AND C	CHORBAJI, MONZER R			
BECTON DIC	KINSON AND COMP				
[THE WEBB ]	LAW FIRM]	ART UNIT	PAPER NUMBER		
FRANKLIN LAKES, NJ 07414-1880			1744		

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  Attachment(s)  1) Notice of References Cited (PTO-892)			λh /				
Examiner    Art Unit   MONZER R CHORBAI    1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1744   1745	(	Application No.	Applicant(s)				
MONZER R CHORBAJI  1744  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address - Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  THE MAILING DATE OF THIS COMMUNICATION.  If the period for right specified above is less than this; (30) days, any any version and chairs; (30) (MONTHS from the manage daw of this communication.  If the period for right specified above is less than this; (30) days, any white ine statutes printing and of this communication.  If the period for right specified above is less than this; (30) days, any white ine statutes printing and of this; (30) days will be considered dimely.  If the period for right specified above is less than this; (30) days, any white the statutes printing and of this communication.  Any analy received by the Offical later than those months after the mailting date of this communication, even if streety filed, may reduce any search precision is produced the office later than those months after the mailting date of this communication, even if streety filed, may reduce any search precision is produced.  This action is FINAL.  2b) [Mis action is non-final.  3] [Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) [Claim(s)	Office Action Comments	10/736,489	ZHAO ET AL.				
The MALING DATE of this communication appears on the cover sheet with the correspondence address − Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions for time may be available under the growing of 37 CFR 1136(s). In no event, however, may a reply be timely filed  Extensions for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If the period for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If NO period for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If the period for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If the period for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If the period for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If the period for reply aspecified above is less than thirty (30 days, a reply within the addition) minimum of liferity (30) days will be considered timely.  If the period for reply aspectified to a period for reply will, and the remaining days of the communication.  If the period for reply aspectified to the merits is considered timely than the addition of the communication.  If the period for reply aspectified to period for reply will, and the period for reply addition and the remaining days of the merits of the merits of the period for reply addition and the period for reply addition and the period for reply addition.  If the period for reply aspectified to by the Examiner.  If the period for reply aspectified to by the Examiner.  If	Onice Action Summary	Examiner	Art Unit				
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ② MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of lines may be available under the provisions of 37 CFR 1.13(b). In no event, however, may a reply be timaly filled  Extensions of lines may be available under the provisions of 37 CFR 1.13(b). In no event, however, may a reply be timaly filled  If No period for reply is specified above, be maintained statutory protected will apply and will expire SIX (5) MONTHS from the mailing date of this communication.  Fasile to incommend patient from adjustment Set 37 CFR 1.704(b).  Status  1 SN Responsive to communication(s) filed on 15 December 2003.  2a  This action is FINAL.  2b  This action is non-final.  3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s) 1.45 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  6   Claim(s) 1.45 is/are rejected.  7)  Claim(s) is/are allowed.  6   Claim(s) 1.45 is/are rejected to.  8)  Claim(s) 3.45 is/are rejected to.  8)  Claim(s) 3.45 is/are repected to by the Examiner.  10  The drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.  Application Papers  9  The specification is objected to by the Examiner.  10  The drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.  Application Papers  9  The specification is objected to by the Examiner.  10  The drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.  Application Papers  9  The specification is objected to by the Examiner.  10  The drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.  Application Papers  9  The specification is objected to by the Examiner.  10  The drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.  11  The							
THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CPR 1.13(a). In no event, however, may a reply be timely filed after SIX (8) MONITS from the making date of this communication.  If NO period for reply is specified above, the machine is accommunication.  If NO period for reply is specified above, the machine is accommunication.  Failure to reply within the set or extended period for reply within the statutory minimum of their, 00) days will be considered fromly.  If NO period for reply is a policial above, the machine is active to previous and application to become ABANDONED (13 U.S.C. § 133). Any reply seveded by the Differ above, the machine after the making date of this communication, even if timely filed, may reduce any section as a policial to the section of the communication of the control parent form edipartment. Sets 37 CFR 1.74(b).  Status  1)  Responsive to communication(s) filed on 15 December 2003.  2a)  This action is FINAL.  2b)  This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s) 1-45 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  6)  Claim(s) 1-45 is/are rejected.  7)  Claim(s) 1-45 is/are rejected.  7)  Claim(s) 1-45 is/are rejected to the structure of the communication of the provision of the decimal of the second of the communication.  Application Papers  9)  The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Application paper as subject to restriction and/or election requirement.  Application paper as a subject to restriction and/or election requirement.  Application paper as a subject to restriction of the drawing(s) be held in abeyance. See 37 CFR 1.121(d).  11) The drawing(s) filed on is a subject to the prior	·						
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2a)  This action is FINAL.  2b)  This action is non-final.  3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s)  1-45 is/are pending in the application.  4a) Of the above claim(s)  is/are withdrawn from consideration.  5)  Claim(s)  is/are allowed.  6)  Claim(s)  is/are objected to.  8)  Claim(s)  are subject to restriction and/or election requirement.  Application Papers  9)  The specification is objected to by the Examiner.  10)  The drawing(s) filed on  is/are: all accepted or b∫ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a)  All b)  Some * c)  None of:  1.  Certified copies of the priority documents have been received.  2.  Certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  Attachment(s)  1)  Notice of Praftspersor's Patent Drawing Review (PTO-948)  3)  Notice of Informal Patent Application (PTO-152)	Status						
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	Sterit Application (F. 10-132)						

#### **DETAILED ACTION**

# This general action is in response to the application filing date of 12/15/2003 Claim Rejections - 35 USC § 102

**1.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-3, 8, 12-13, 16-18, 21-22, 24-25, 28-34, 36-38 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozimor et al (U.S.P.N. 6,231,936).

With respect to claims 1, 17 and 32, the Kozimor reference teaches a method for designing radiation stable (col.1, lines 7-10) prefilled syringes (col.8, lines 47-50) that is to be sterilized by gamma irradiation (col.2, lines 36-39, col.4, lines 10-15, col.10, lines 31-46 and col.9, lines 6-8).

With respect to claims 2-3, 21-22, 33-34 and 36-37, the Kozimor reference discloses a therapeutic drug in a container (col.8, lines 47-49) for injection into the body where the container is a bag (col.8, lines 65-67) or a syringe (col.8, line 48).

With respect to claims 8, 12-13, 25, 28-29, 38 and 42-43, the Kozimor reference teaches a container manufactured from polypropylene (col.5, lines 43-44) that includes an additional polymer at, for example, 8 weight percent (col.4, lines 42-43).

With respect to claims 30-31, the Kozimor reference discloses a therapeutic drug in a container (col.8, lines 47-49) for injection into the body where the container is a bag (col.8, lines 65-67) or a syringe (col.8, line 48).

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With respect to claims 16, 18 and 24, the Kozimor reference teaches irradiating with gamma radiation at doses of 2.5, 5.0, 7.5 (col.4, lines 23-27) and up to 10 Mrad (col.4, lines 22-23, for example, 10 Mrad is equal to 100 KGy) and also teaches irradiating prefilled syringes (col.8, lines 47-49) such that irradiating prefilled syringes necessarily means syringes that have already been sealed prior to irradiation step.

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claim 1 and further in view of the admitted state of the prior art.

With respect to claims 6-7, the Kozimor reference fails to teach placing medium irradiation limitations on ultraviolet absorbance at certain wavelength range value and on the concentration of hydrogen peroxide; however, the specification on page 2, lines 10-14, teaches that the required UV absorbance level is below 0.2 at 220-340 nm and the presence of hydrogen peroxide along with other oxidizing agents should be below 3.4ppm. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference to include limits on UV absorbance value and on hydrogen peroxide value in order to comply with the European and/or U.S. Pharmacopoeia guidelines as taught in the specification (page 2, lines 1-14).

Claims 4-5, 23 and 35 are rejected under 35 U.S.C. 103(a) as being 7. unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claims 2, 1, 17 and 32 respectively and further in view of Jacobs et al (Acta Pharm, IDS).

With respect to claims 4-5, 23 and 35, the Kozimor reference fails to teach saline water as the medium and the pH of the medium after irradiation between about 4.5 and about 7.0; however, the Jacobs reference teaches gamma irradiation of saline water (table 1) and, for example a pH of 5.0 for saline water after gamma irradiation (table 2).

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Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference to include irradiating saline water as taught by the Jacobs reference since saline water is used for injections (abstract).

8. Claims 9, 14-15, 26, 39 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claims 8, 25 and 38 and further in view of Williams et al (U.S.P.N. 4,994,552).

With respect to claims 9, 14-15, 26, 39 and 44-45, the Kozimor reference fails to teach the following: the composition of the container includes a clarifying agent such as dibenzylidene sorbitol alkyl thioether with a clarifying amount, a mobilizing additive such as a hydrocarbon oil and the stabilizer is bis (4-piperidinyl) diester of a dicarboxylic acid. The Williams reference teaches the following: the composition of the container includes a clarifying agent such as dibenzylidene sorbitol alkyl thioether with a clarifying amount (col.8, lines 45-47), a mobilizing additive such as a hydrocarbon oil (col.2, lines 43-44) and the stabilizer is bis (4-piperidinyl) diester of a dicarboxylic acid (col.4, lines 59-61). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference by including a clarifying agent, a mobilizing additive and a stabilizer as taught by the Williams reference since they produce a polymeric composition of high clarity which may be radiation sterilized without degradation of its mechanical properties due to radiation (col.2, lines 30-32).

9. Claims 10-11, 27 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claims 8, 25 and 38 and further in view of Saito et al (U.S.P.N. 6,437,048).

With respect to claims 10-11, 27 and 40-41, the Kozimor reference fails to teach including a nucleating agent such as 2,2'-methylene-bis (4,6-di-t-butylphenol) phosphate salt; however, the Saito reference, which is in the art of designing medical articles made of polyolefin material, teaches the use of aluminum 2,2'-methylene-bis (4,6-di-t-butylphenol) phosphate (col.29, lines 23-25). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference by including a nucleating agent as shown by the Saito reference in order to ensure excellent glossiness and reflection of the obtained olefin article (col.28, lines 34-36).

**10.** Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claim 18 and further in view of Vellutato (U.S.P.N. 6,123,900).

With respect to claim 19, the Kozimor reference teaches that prefilled syringes containing a drug will be packaged for delivery (col.8, lines 47-48), but fails to explicitly teach irradiating packaged containers. The Vellutato reference teaches irradiating pharmaceutical compositions after being packaged inside a carton with gamma radiation (col.3, lines 1-9, col.4, lines 50-52 and col.5, lines 1-5). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference by gamma irradiating already packaged

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container as taught by the Vellutato reference since Gamma radiation has a high penetration capability (col.5, lines 22-26).

With respect to claim 20, the Kozimor reference teaches that the packaging includes blister packing (col.8, lines 19-20).

### Conclusion

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

**12.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHN KIM can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji M R
Patent Examiner
AU 1744
09/29/2005

SUPERVISORY PATENT EXAMINER